REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejection of all the claims now in the application (i.e. Claims 1-15, and 17-21) is respectfully requested in view of the foregoing amendments and the following remarks.

Note that the amendments to claims 1, 14 and 17 were for consistency purposes only. The word "vertebra" should read "vertebrae" as in the Specification.

Initially, the Examiner rejected claims 1-13, and 17-20 as failing to comply with the first paragraph of 35 U.S.C. § 112 in that the language added to claims 1 and 17 in the Response to the last Office Action was not supported in the Specification and is new matter. It appears that the Examiner has interpreted the language added to the claims as referring to the outer perimeter of the claimed intervertebral prosthesis and not to the end faces which contact the vertebral plates as claimed in claims 1 and 17. These surfaces are discussed in the last sentence of paragraph 26 of the Specification and shown as surfaces 108 and 110 in FIG. 6. It appears the Examiner has interpreted the claim language to read on the outer perimeter of the prior art implant and not the contact surfaces as intended.

Applicant considers that one of ordinary skill in the prosthetic spinal art would understand the claim language which refers to the "vertebral end plates" to refer to the contact faces of the vertebrae. Applicant is attaching a chapter from "On development of an artificial intervertebral disc" by Marcus Franciscus Eijkelkamp, University Library Groningen (2002) ISBN 90-367-1722-1 relating to developments of artificial intervertebral discs which Chapter 5 deals with the geometry of the human intervertebral disc and shows in paragraphs 5.1 and 5.2 the concavity of the vertebral end plate discussed in the Specification and referred to in claims 1 and 17. It is Applicant's position that one of ordinary skill in the vertebral prosthesis art would understand that the Applicant was not referring to the outer peripheral surface but rather the bone contacting surfaces of the implant. Again, these surfaces 108, 110 are shown in FIG. 6 and discussed at the end of paragraph 26 of the Specification.

The Examiner apparently admits that none of the prior art cited shows the claimed contact surface structure by stating that he is giving the language the broadest interpretation in order to read on the prior art. His interpretation is that since the outer periphery of the prior art is circular it inherently has an outer curvature corresponding to the inward curvature of the vertebrae. Clearly, the Examiner is referring to the outer peripheral surface

shown in the prior art and not the contact surfaces of the prosthesis that engage the vertebral end plates. Applicant wishes to point out that the test is not the broadest interpretation but the broadest "reasonable" interpretation consistent with the one that those skilled in the art would reach. *See in re Cortright,* 165 F3d 1353, 49 U.S.P.Q. 2nd 1464 (Fed. Cir. 1999). In addition when the Applicant states the meaning that claimed terms are intended to have, the claims are examined with that meaning in order achieve a complete exploration of the Applicant's invention and its relation to the prior art. *See in re Zletz*, 893 F2nd 319, 13 U.S.P.Q. 2nd 1320 (Fed. Cir. 1989). Here, both the Specification paragraph 26 and FIG. 6 thereof, make it clear to one of ordinary skill in the art that the surfaces being talked about are the end plate surfaces and the longitudinal upper and lower contact faces of the vertebral prosthesis.

Applicants believe the claims as filed in the Response of July 21, 2004 are fully supported by the Specification. Applicant respectfully requests the Examiner reconsider his final rejection and withdraw the same and pass the application to issue. Alternately, Applicant request that the Examiner enter the amendments contained herein making the remarks and the attached article part of the record to place the application in better condition for Appeal.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

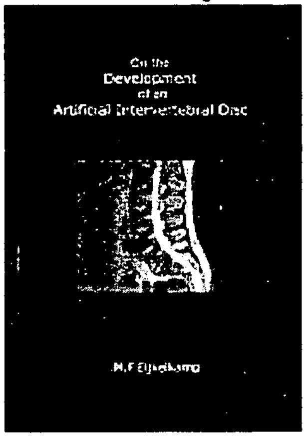
If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: December 20, 2004

Respectfully submitted,

By

Raymond W. Augustin
Registration No.: 28,588
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant



On the development of an artificial intervertebral disc [Online Resource] / Marcus Franciscus Eijkelkamp. - [S.l. : s.n.] ; [Groningen : University Library Groningen] [Host], 2002. - Online. : ill Auteursnaam op omslag gedrukte versie: M.F. Eijkelkamp. - Auteursnaam op franse titelpag. gedrukte versie: Mark Eijkelkamp. - Ook verschenen in gedrukte vorm. - Proefschr. Rijksuniversiteit Groningen. - Met lit. opg. - Met samenvatting in het Nederlands. ISBN 90-367-1722-1 (ISBN gedrukte versie)

Totaal aantal pagina's / Total number of pages: 106

---

bestel een gedrukt exemplaar / order a printed copy

- PDF files
    - titlepages/contents [120 Kb]
    - chapter 1 [193 Kb]
    - chapter 2 [141 Kb]
    - chapter 3 [281 Kb]
    - chapter 4 [217 Kb]
    - chapter 5 [190 Kb]
    - chapter 6 [194 Kb]
    - chapter 7 [66 Kb]
    - samenvatting [30 Kb]
    - summary [33 Kb]
    - thesis [1106 Kb]

Voor vragen: i service bibliotheek RuG
Installeer een Adobe Acrobat viewer om PDF files te bekijken.
Install an Adobe Acrobat viewer to view PDF files.

begin pagina

Chapter 5 The geometry and shape of the human intervertebral disc

M.F. Eijkelkamp, J.P. Klein, A.G. Veldhuizen, J.R. van Horn, G.J. Verkerke

Abstract

Goal of this study was to detemine the height, wedge angle of the intervertebral discs and concavity of the lumbar vertebral endplate. The wedge angle was studied with X-ray (63 subjects) and MRI (10 subjects). The intervertebral disc height and vertebral endplate depth were measured only with MRI. Subjects were selected from patient scans, which had no sign of degeneration or irregularities.

The wedge angle increases from 4.4 degrees for T12-L1 to 13.1 degrees for L5-S1 with X-ray and 4.9 to 13.0 degrees with the MRI method. The average anterior height ranges from 9.0 for T12-L1 up to 14.2 mm for L4-L5, the middle height ranges from 9.1 for T12-L1 to 14.2 mm for L3-L4, and the posterior height ranges from 6.5 for T12-L1 to 9.9 mm for L3-L4. The concavity of the lumbar vertebral endplates generally increases from T12 to L5 , the superior side of S1 has no concavity. The maximal average depth of the vertebral endplate relative to the edge is 1.7 mm. with a range of -1.1 to 3.67 mm.

Submitted to Spine

THIS PAGE BLANK (USPTO)

Chapter 5: The geometry and shape of the human intervertebral disc

5.1. Introduction

For the development of an Artificial Intervertebral Disc (AID) the geometry of the AID is very important. To prevent a change in shape of the vertebral column, to prevent migration of the AID in the vertebral column and to stimulate the growth of bone onto the surface of the intervertebral disc, the disc should get the same geometry as the original intervertebral disc (IVD) (3). The posterior and anterior disc height, the sagittal diameter and the transversal diameter of the AID should resemble the dimensions of the IVD.

The vertebral endplates of the lumbar vertebrae are concave, especially for older patients (7). Therefore, to adapt the endplate of the AID to the vertebrae, the AID endplate should be given a convex shape. The value and range and place of the maximal concavity of the vertebral endplate has up to now not been studied.

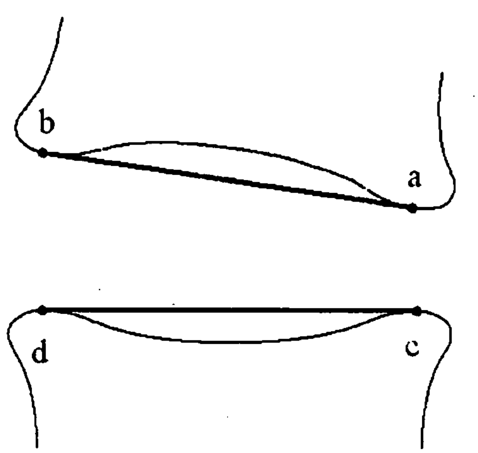


Figure 5-1: The measurement of the wedge angle of the lumbar vertebrae with X-ray. The measurement points were the most protruding superior or inferior points of the vertebrae, because that are the contact points of an artificial disc

Goal of this study was to measure the height and the wedge angle of the intervertebral disc and the concavity of the vertebral endplates.

5.2. Material and Methods

To determine the geometry and shape of vertebrae, two methods are available, X-ray and MRI. Both methods were used for determining the wedge angle. X-ray data were used, because many X-ray recordings were available. MRI data were used, because the quality is superior to that of X-rays. Quantity, however, is less. To determine the height of the intervertebral disc and the concavity of the vertebral endplates only the high-quality MRI data could be used.

5.2.1. X-ray studies

From the patient records of the University Hospital Groningen, patient X-rays were selected with no sign of degeneration or irregularities of the IVD's. In total 63 subjects of 18 to 65 years were measured, of these 3 had six lumbar vertebrae and were excluded. The wedge angle was measured from these lateral X-rays. The angle between two lines drawn from the edges of the IVD was determined twice with software of the X-ray scanner (Figure 5-1). The mean was calculated from the two measurements.

5.2.2. MRI studies

From the patient records of the University Hospital Groningen, 10 patient MRI's were selected with no sign of degeneration of the IVD's. The age of the patients ranged from 22 to 56 years. The MRI measurements were performed with a Siemens MRI.

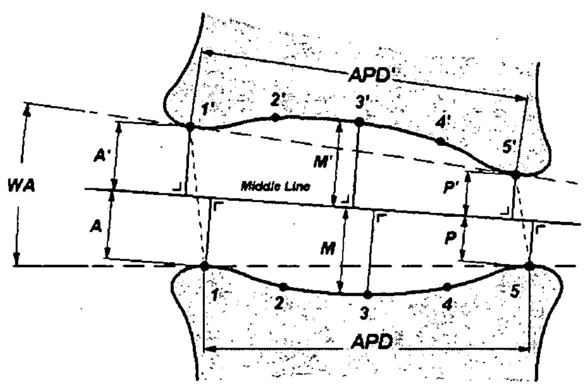


Figure 5-2: Schematic design of the revised method of Brinkman: The anterior, middle and posterior disc height are determined by the rectangular distance to the middle line of the intervertebral disc.
Note: The superior 'vertebra' is translated forward for a clearer view.

The distance between the slices of the scans was 4.4 mm. For this study, the lateral scans of the vertebral column were used. The surfaces of the vertebral endplates of T12 inferior to S1 superior were reconstructed by measuring the 3-D coordinates of 5 points on the surfaces in each scan of the MRI (Figure 5-2). The points one and five are situated on the rim of the vertebra. Not the most anterior or posterior point was chosen, but the points that are supposed to come in contact with the artificial disc, being the most protruding points of the vertebra in the direction of the intervertebral disc. Point 3 is defined on the surface of the vertebra, halfway between points 1 and five, point 2 and 4 are defined halfway between point 1 and 3, respectively point 3 and 5.

The distance between points 1 and 5 determines the sagittal diameter (APD). The anterior (ADH), middle (MDH) and posterior disc height (PDH) of the intervertebral disc are calculated using a revised method of Brinckmann (4) as shown in Figure II. Through the middle points of the lines between points 1 and 1' respectively 5 and 5' a

middle line is drawn. The perpendicular distance of the points 1, 3, 5 and 1', 3' and 5' to the middle line was calculated (P, A, M, P', A' and M',). Then the anterior, middle and posterior disc height were calculated with equation 1:

$$\begin{aligned} ADH &= A + A' \\ MDH &= M + M' \\ PDH &= P + P' \end{aligned} \qquad (1)$$

The wedge angle of the intervertebral disc was calculated in two ways:
1: MRI-normals method:
The wedge angle of the intervertebral disc was calculated from the normals of the adjacent endplate planes.

2: MRI-heights method:
The wedge angle was calculated from the posterior and anterior intervertebral disc heights using equation 2:

$$WA = \sin^{-1} \frac{ADH - PDH}{\frac{1}{2}(APD + APD')} \qquad (2)$$

with WA the wedge angle.

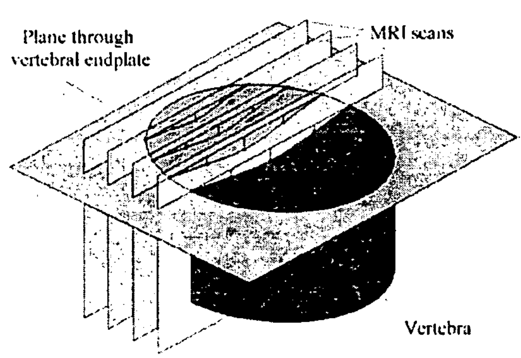


Figure 5-3: Schematic design of the method to determine the depth of the vertebral endplates

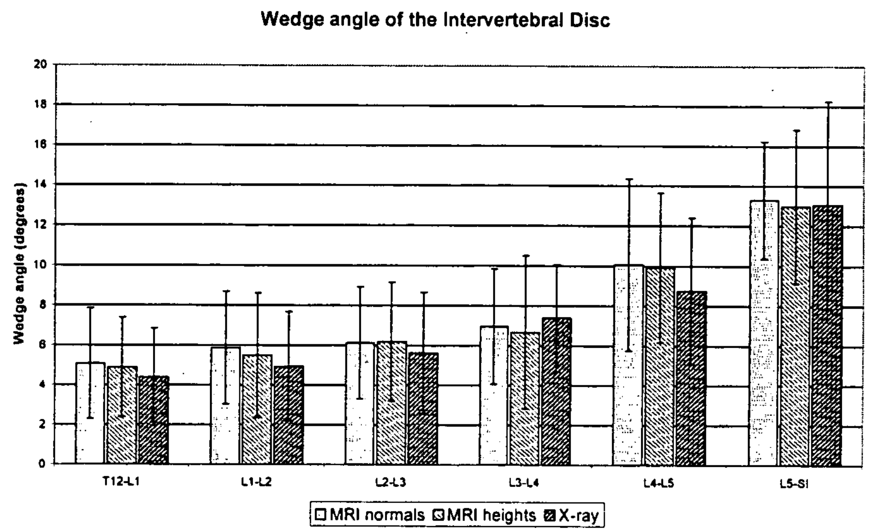
The concavity of the vertebrae is determined using the method shown in Figure 5-3.

Through all the points on the outer rim of the vertebral endplate of each MRI scan an 'endplate plane', was drawn, using the 'least-square method'. For each scan, the perpendicular distance of the five points of the vertebral endplate to the endplate plane was calculated. Each perpendicular distance is averaged over the three most median MRI scans of the vertebrae. The resulting 'depths' function as measure of the concavity.

5.3. Results

The wedge angles measured with the X-ray studies and MRI studies are given in Figure 5-4. The wedge angle increases from T12- L1 to L5-S1. The wedge angle calculated with the MRI-normals method is slightly larger than the angle measured with the MRI-heights method. The height of the IVD is given in Figure 5-5. The height in the middle of the intervertebral disc is larger than the anterior and posterior height, except for L4-

Figure 5-4: Wedge angle (with standard deviation) of the lumbar intervertebral discs in degrees with MRI-heights method, MRI-normals method and with X-ray measurements



L5 and L5-S1, due to the larger wedge angle of these levels.

The average depth of the lumbar vertebral endplates is shown in Figure 5-6. The depth of single endplates ranges from -1.1 mm (convex) up to 3.6 mm. In general, the depth of the vertebra of the lumbar spine increases from L12 to L5. However, S1 shows no depth. The maximum depth of the vertebral endplates is located to the posterior side of the vertebral endplates at about two-third of the sagittal diameter.

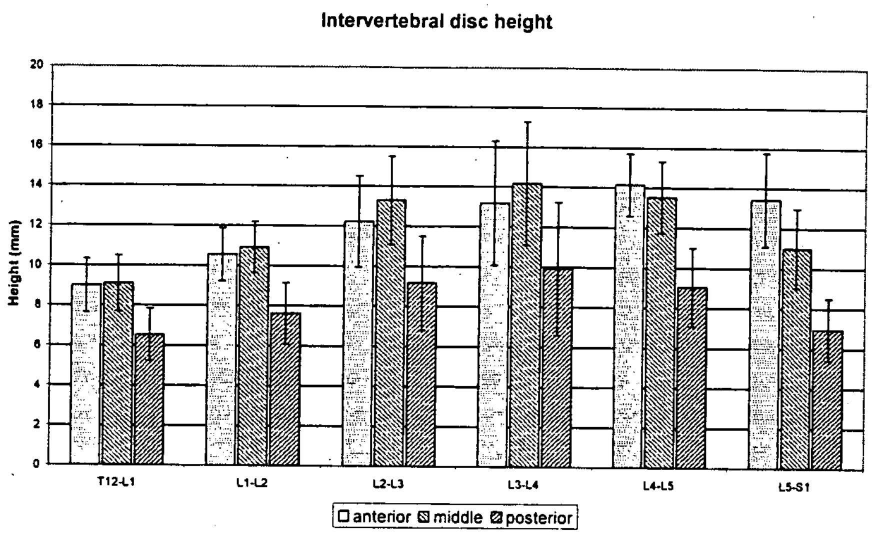
5.4. Discussion

An artificial disc, which has a stiffness similar to the stiffness of the natural intervertebral disc should have a wedge angle similar to the wedge angle of the natural intervertebral disc to prevent the vertebral column to be forced into an unnatural position. From this study it appeared that the wedge angle of L5-S1 is much larger than the wedge angle of the other intervertebral disc levels. Therefore, artificial discs have to be available in different wedge angles at least for the large wedge angle of L5-S1. From these measurements, an artificial disc for T12-L1 to L3-L4 could have a wedge angle of

5 to 6 degrees, L5-S1 would need a wedge angle of about 13 degrees. For L4-L5, a wedge angle of about 9 degrees would be best.

The difference between the two methods to measure the wedge angle with MRI was limited. The differences of the X-ray method compared to the MRI method are within

Figure 5-5: Anterior (a) middle (m) and posterior height of the intervertebral disc

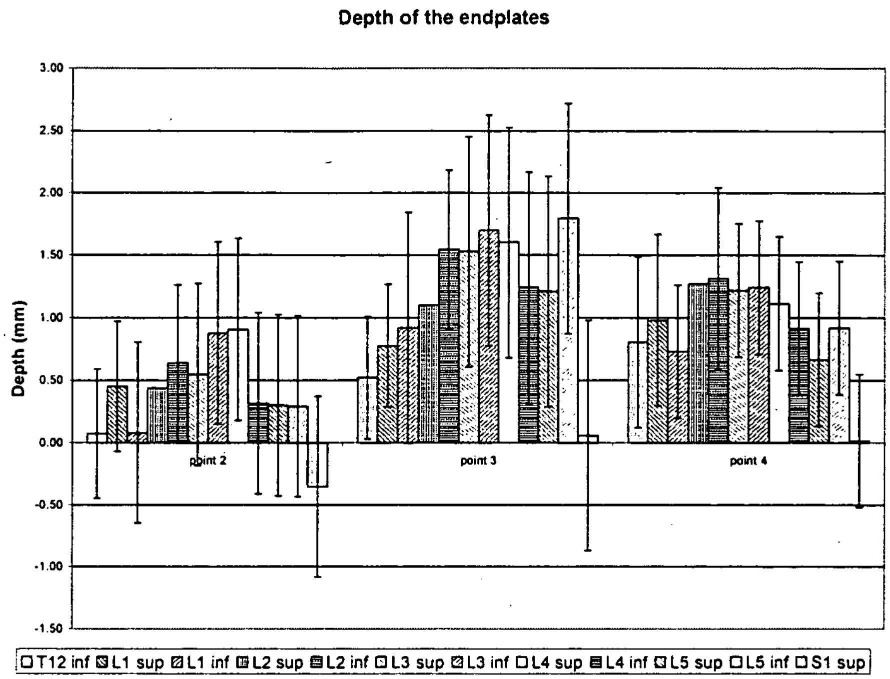


20 percent. In the study of Aharinejad (1), the wedge angle was measured with CT scans and MRI, and appeared to be zero. From the results of Nissan (5), wedge angles were calculated very close to our results. From results of Tibrewal (6) and Amonoo-Kuofi (2) wedge angles were found larger than ours, especially for the higher lumbar levels. For L5-S1, the results are comparable. Possible causes of the difference in results is the choice of the measured points with the X-ray method. With the MRI method, there is sometimes a difference in image quality or clarity between bone and surrounding tissues. We chose the MRI-scan with the clearest difference between bone and surrounding tissues.

The heights of the intervertebral discs found in our study are smaller than the heights found by Amonoo-Koufi (2) (especially the anterior heights), but are comparable with the heights found by Tibrewal (6)and Nissan (5). Posterior disc heights are comparable with Aharinejad, anterior disc heights are larger. The difference with the results of Amonoo Kuofi is probably due to the radiographic magnification that occurs when making X-ray scans. Because the difference in intervertebral disc height, the artificial disc has to be available in different heights, from 8 to 14 mm average disc height (the average of the anterior and posterior disc height).

From the study of Twomey (7) is known that the depth of the vertebral endplates increases with age, due to decreased bone density. The largest depth of the vertebral

Figure 5-6: Depth (with standard deviation) of the lumbar vertebral endplates at 3 points



endplates was located posteriorly of the middle of the vertebrae.
From our results, the average depth of the lumbar vertebral endplates in the middle of the disc is about 1.2 mm (range 0.1 to 1.8 mm). Just like Twomey found, the maximum depth of the vertebral endplates is located at the posterior half of the vertebrae.

5.5. Conclusions

The wedge angle of the lumbar vertebrae increases from T12- L1 to L5-S1. Differences in results between X-ray method and MRI are less than 20 percent. The height in the middle of the intervertebral disc is larger than the anterior and posterior height, except for L4-L5 and L5-S1, due to the larger wedge angle of these levels.

The concavity of the endplates in terms of the distance (depth) to a plane through the edge of the endplate ranges from -1.1 mm (convex) to 3.6 mm. The concavity of the vertebra of the lumbar spine increases from L12 to L5. S1 shows no concavity. The maximum depth of the vertebral endplates is located to the posterior side of the vertebral endplates at about two-third of the sagittal diameter.

5.6. References

1. Aharinejad S, Bertagnoli R, Wicke K, Firbas W, Schneider B. Morphometric analysis of vertebrae and intervertebral discs as a basis of disc replacement. Am J Anat 1990; 189: 69-76.
2. Amonoo KH. Morphometric changes in the heights and anteroposterior diameters of the lumbar intervertebral discs with age. J Anat 1991;175: 159-68.
3. Eijkelkamp MF, Donkelaar CC, Veldhuizen AG, Horn JR, Verkerke GJ. Requirements for an artificial intervertebral disc. Int J Art Organs 2001; 24: 311-21.
4. Frobin W, Brinckmann P, Biggemann M, Tillotson M, Burton K. Precision measurement of disc height, vertebral height and sagittal plane displacement from lateral radiographic views of the lumbar spine. Clin Biomech 1998; 21, S1-64.
5. Nissan M, Gilad I. Dimensions of human lumbar vertebrae in the sagittal plane. J Biomech 1986; 19: 753-8.
6. Tibrewal SB, Pearcy MJ. Lumbar intervertebral disc heights in normal subjects and patients with disc herniation. Spine 1985; 10: 452-4.
7. Twomey LT, Taylor JR. Age changes in lumbar vertebrae and intervertebral discs. Clin Orthop 1987; 97-104.